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## 235.40

### Review of Indications for Infant Formulas

#### Overview

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<b>Introduction</b>	This policy reviews the indications for commonly prescribed infant formulas and identifies the primary contract and <b>contract non-exempt</b> infant formulas.
<b>Providing milk for formula</b>	Federal WIC regulations do not permit the provision of cow's milk or goat's milk to infants less than one year old.
<b>Medical documentation</b>	The primary contract infant formulas do <u>not</u> require <b>medical documentation and should be the first choice of issuance to the majority of healthy full-term infants.</b>
<b>Policy reference</b>	<ul style="list-style-type: none"><li>• WC-04-34-P: Implementation of the Infant Formula Cost Containment Provisions of Public Law 108-265</li><li>• <b>WIC Policy Memorandum #2014-1 Changes to Abbott Infant Formula Product Line</b></li><li>• <b>WIC Policy Memorandum #2014-1A Clarification on Medical Documentation for Infant Formula Issued in Food Packages I and II</b></li></ul>
<b>Other references</b>	<ul style="list-style-type: none"><li>• Committee on Nutrition. Soy protein-based formulas: Recommendations for use in infant feeding. <i>Pediatrics</i> 101 (1):148-153, 1998.</li><li>• American Academy of Pediatrics: <i>Pediatric Nutrition Handbook</i>, Sixth Edition. Elk Grove Village, Illinois, 2009.</li><li>• Committee on Nutrition. Iron-fortification of infant formulas. <i>Pediatrics</i> 104(1):119-123, 1999.</li></ul>
<b>In this policy</b>	This policy covers the following topics.

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## Iron-fortified Cow's Milk-based Infant Formula

<b>Introduction</b>	<p>Iron-fortified cow's milk-based formula is indicated as a substitute for human milk when:</p> <ul style="list-style-type: none"> <li>• Mothers choose not to breastfeed,</li> <li>• Mothers stop breastfeeding before their infant's first birthday,</li> <li>• Mothers choose to supplement breastfeeding,</li> <li>• Breastfeeding is medically contraindicated, or</li> <li>• Supplementation is needed for breastfed infants who are not gaining weight adequately.</li> </ul>
<b>Minor feeding problems in otherwise healthy infants</b>	<p>Most healthy infants tolerate cow's milk-based formula without problems. Fussiness, looser stools, and spitting up do not indicate feeding problems in infants who are adequately gaining weight and appear otherwise healthy. However, some infants switch to cow's milk-based lactose-free formulas or soy-based formulas and respond positively to the switch for reasons not totally understood. Most of these infants can return to a lactose-containing formula within a month without problems.</p>
<b>Formulas with added long-chain fatty acids</b>	<p>Infant formulas with added docosahexanoic acid (DHA) and arachidonic acid (ARA) were introduced in the U.S. in 2002. FDA concluded that the addition of these fatty acids to term formulas was safe. These formulas are one of many alternative products available for term infants.</p> <p><u>Note:</u> Iron-fortified cow's milk-based formulas contain precursors of these fatty acids from which healthy term infants can synthesize DHA and ARA.</p>
<b>Primary contract infant formula</b>	<p>Similac Advance <b>Stage 1</b></p> <p><u>Note:</u> This formula is a kosher product.</p>

## Soy-based Infant Formula

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<b>Introduction</b>	Soy-based infant formulas use an alternate source of protein. These formulas are also lactose-free. All soy-based infant formulas are iron-fortified.
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<b>Indications</b>	<p>Soy-based formulas may be recommended for term infants with:</p> <ul style="list-style-type: none"><li>• Galactosemia,</li><li>• Lactose intolerance during recovery from a diarrheal illness,</li><li>• Lactase deficiency,</li><li>• A vegetarian-based diet, and</li><li>• IgE mediated reaction to cow's milk-based formula.</li></ul>
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Note: Soy-based formulas are not recommended for preterm infants weighing <1800 grams at birth, prevention of colic or allergy, or cow's milk protein-induced enterocolitis or enteropathy.

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<b>Cow's milk allergy</b>	<p>Cow's milk allergy (or hypersensitivity) develops in 2-3 percent of infants, but 85 percent of these children outgrow the sensitivity by their third birthday. Cow's milk protein may induce:</p> <ul style="list-style-type: none"><li>• <b>Immunoglobulin E (IgE) mediated reactions</b> evident from eczema, rhinitis (runny nose), respiratory symptoms such as asthma and wheezing, and urticaria (hives). Most infants with these reactions to cow's milk protein tolerate soy-based formulas.</li><li>• <b>Enteropathy</b> (intestinal disease) or <b>enterocolitis</b> (inflammation of the intestine and colon). Vomiting, diarrhea, and failure to thrive characterize these illnesses. Colitis with gastrointestinal bleeding and colic may also occur. Small bowel damage often occurs, allowing absorption of intact proteins such as soy protein. Because up to 60 percent of infants with cow's milk induced enteropathy will also be sensitive to soy proteins, protein hydrolysate or synthetic amino acid formulas are indicated (see page 7 in this policy).</li></ul>
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## Soy-based Infant Formula, Continued

### Lactose intolerance

Clinical lactose intolerance may occur with reduced lactase activity, depending on the extent of the reduction. Symptoms include excessive gas production, abdominal distention, and cramping. Vomiting is rare with lactose intolerance. Eczema, rhinitis (runny nose), asthma, wheezing, and urticaria (hives) do not occur with lactose intolerance.

Congenital lactase deficiency is extremely rare. When it does exist, symptoms of clinical lactose intolerance will be evident with the first feedings.

### Secondary lactase deficiency

In infancy, lactose is more likely to be poorly absorbed during viral gastroenteritis due to damage to the intestinal villi. This secondary lactase deficiency usually resolves when the illness ends. The table below describes feeding recommendations for the post diarrheal phase.

IF the infant...	THEN...
is otherwise healthy	continue the usual feeding (human milk or cow's milk-based formula).
<ul style="list-style-type: none"> <li>• had inadequate weight gain <b>or</b></li> <li>• prolonged diarrhea</li> </ul>	<ul style="list-style-type: none"> <li>• feed lactose-free formula* until recovery from the diarrhea is complete (typically 1-2 weeks), and</li> <li>• rechallenge with lactose-containing formula within one month.</li> </ul>

\*A soy-based formula or a cow's milk-based lactose-free formula.

### Primary contract infant formula

Gerber Good Start Soy

Note: This formula is a kosher product.

## Cow's Milk-based Lactose-free Infant Formula

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**Introduction** This type of formula contains cow's milk protein and is lactose-free. The indications for this type of formula are slightly different than for soy-based infant formulas.

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**Decision table** The table below summarizes appropriate uses for cow's milk-based lactose-free infant formulas.

IF the infant...	THEN...
has congenital lactase deficiency	<ul style="list-style-type: none"> <li>offer the choice between the cow's milk-based lactose-free and soy-based formulas.</li> </ul>
<ul style="list-style-type: none"> <li>is recovering from diarrheal illness <b>and</b></li> <li>had prolonged diarrhea <b>or</b> inadequate weight gain</li> </ul>	<ul style="list-style-type: none"> <li>offer the choice between the cow's milk-based lactose-free and soy-based formulas, and</li> <li>explain that a lactose-containing formula will be reintroduced in 4-6 weeks.</li> </ul>
<ul style="list-style-type: none"> <li>has minor intolerance to cow's milk protein <b>and</b></li> <li>appears otherwise healthy <b>and</b></li> <li>is growing adequately</li> </ul>	<ul style="list-style-type: none"> <li>offer the choice between cow's milk-based lactose-free formula and soy-based formula, and</li> <li>explain that a lactose-containing formula will be reintroduced in 4-6 weeks.</li> </ul>
has respiratory or skin reactions to cow's milk-based formula	<ul style="list-style-type: none"> <li>offer a soy-based formula, and</li> <li>continue its use until the first birthday.</li> </ul>

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**Contract non-exempt formula** Iowa WIC does not provide a 100% lactose free infant formula. Similac Sensitive is a standard milk-based 99.8% lactose-free infant formula indicated for infants with lactose sensitivity and lactose intolerance.

Notes:

- This formula requires medical documentation as it does not meet the Federal WIC regulations found in Table 4 of 7 CFR 246.10(e)(12) and contains 19 calories per ounce instead of the required 20 calories per ounce.
  - This formula is a kosher product.
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## Pre-thickened Infant Formula

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**Introduction** This formula has a higher viscosity before feeding yet flows smoothly through a standard nipple. When ingested, its viscosity increases further in the acid environment of the stomach. Because the thickening agent is integrated into the formulation of the product, the nutrient ratios and caloric density of the formula remain similar to a cow's milk-based infant formula.

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**Indication for use** This formula may be indicated for infants with gastroesophageal reflux (GER) or frequent regurgitation associated with intense irritability, feeding disorders, or failure to thrive. GER is distinguished from simple regurgitation (or spitting up) by its frequency and association with other feeding difficulties.

Note: This product is not recommended for preterm infants.

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**Contract non-exempt formula**

Similac for Spit Up

Notes:

- This formula requires medical documentation as it does not meet the Federal WIC regulations found in Table 4 of 7 CFR 246.10(e)(12) and contains 19 calories per ounce instead of the required 20 calories per ounce.
  - This is a kosher product.
  - Similac for Spit Up is also lactose-free.
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## Protein-altered Infant Formulas

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**Introduction** Infants with significant gastrointestinal symptoms may need a protein-altered formula.

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**Types of protein-altered formulas** There are three types of protein-altered formulas based on the protein source. The table below lists the protein sources and potential indications for use.

Protein source	Indications for use
Amino acids	Significant malabsorption
Casein hydrolysate	<ul style="list-style-type: none"> <li>• Cow's milk protein allergy</li> <li>• Soy protein allergy</li> <li>• Conditions with significant malabsorption</li> </ul>
Whey hydrolysate	Gastrointestinal problems related to protein digestion and absorption such as: <ul style="list-style-type: none"> <li>• Immature gut</li> <li>• Gastroenteritis</li> <li>• Following gastrointestinal surgery</li> <li>• Constipation</li> </ul> <p><u>Note:</u> Whey hydrolysate formula results in softer stools than casein-containing formulas.</p>

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**Composition** These formulas may also contain smaller carbohydrates and medium chain triglycerides (or MCT) to facilitate absorption.

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**Contract non-exempt formula** Similac Total Comfort

**Notes:**

- This formula requires medical documentation as it does not meet the Federal WIC regulations found in Table 4 of 7 CFR 246.10(e)(12) and contains 19 calories per ounce instead of the required 20 calories per ounce.
  - This is a kosher product.
  - Similac Total Comfort is 100% partially hydrolyzed whey protein and has 98% less lactose than standard milk-based formulas.
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## Protein-altered Infant Formulas, Continued

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**Examples**

The table below lists several other examples of protein-altered formulas grouped by protein source.

Protein source	Formula	MCT
Amino acids	Neocate Infant Formula	Yes
Casein hydrolysate	Similac Expert Care Alimentum	Yes
Casein hydrolysate	Nutramigen	No
Casein hydrolysate	Pregestimil	Yes

Note: All of these formulas are non-contract formulas and require medical documentation.

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